UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

SUBJECT: Errata for terrestrial assessment of revised uses, incorporating new aquatic toxicity data and endocrine disruption language for the EFED chapter of the Vinclozolin RED.

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This memo includes a revised Ecological Risk Assessment for Vinclozolin prepared by EFED for the Vinclozolin RED incorporating new label information submitted since the completion of the initial RED chapter in 1997. In addition, a partial assessment incorporating recently submitted toxicity data for estuarine/marine organisms and new endocrine disruption language is included. EFED has concerns about potential adverse chronic reproductive effects on birds and mammals resulting from the use of vinclozolin and also the endocrine disrupting potential of this compound to those species.

Primary concerns from EFED's risk assessment incorporating a re-assessment of uses are the following:

a. Chronic risks to birds and mammals at maximum use rates.
b. Possible endocrine disruption to birds and mammals.
c. There were no new risks from the aquatic (acute estuarine/marine) assessment incorporating the new data and use rates.

The raspberry use has the highest # of applications and shortest interval between applications allowable, thus providing the greatest risk, with the turfgrass/ornamental use next, then onions and lettuce, then snap beans and finally, the canola use exhibiting the least risk. The tables below, which include the new revised uses of vinclozolin clearly show that even with a 7-day foliar dissipation half-life and using average Kenega values, chronic RQ's for birds exceed the level of concern (RQ>LOC of 1.0). Maximum rates resulted in RQs exceeding avian chronic LOCs for all uses.

Table I
Revised Avian Chronic Risk Assessment
(Based on Maximum Application Rates)

Crop	Short Grass		Tall Grass		Broadleaf Plants/Insects		Seeds/sm. Insects	
	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ
Snap beans	180	3.6	82.5	1.7	101.3	2.0	11.3	0.23
Lettuce	315	6.3	144	2.9	177	3.5	20	0.4
Raspberries	450	9.0	206	4.1	253	5.1	28	0.6
Onions	320	6.4	147	2.9	180	3.6	20	0.4
Canola	108	2.16	50	1.0	60.8	1.22	6.8	0.14
Turfgrass/ Ornamentals	375	7.5	172	3.4	211	4.2	23	0.5

Table II
Revised Mammalian Chronic Risk Assessment
(Based on Maximum Application Rates)

Crop	Short Grass		Tall Grass		Broadleaf Plants/Insects		Seeds/sm. Insects	
	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ
Snap beans	180	0.6	82.5	0.28	101.3	0.34	11.3	0.04
lettuce	315	1.1	144	0.5	177	0.6	20	0.06
Raspberries	450	1.5	206	0.7	253	0.8	28	0.09
Onions	320	1.1	147	0.5	180	0.6	20	0.06
Canola	108	0.4	49.5	0.17	60.8	0.2	6.8	0.02
Turfgrass/ Ornamentals	375	1.3	172	0.6	211	0.7	23	0.08

EEC's based on maximum application rate and number of applications with the shortest application interval. Degradation is taken into account with a 7-day foliar dissipation half-life, as reported by BASF in the rebuttal, using the TERECC program.

Snap beans: 0.5 lb ai/a, 2 applications with a 7-day interval.
lettuce: 1 lb ai/a, 3 applications with a 14-day interval.
Raspberries: 1 lb ai/a, 4 applications with a 7-day interval.
Onions: 1 lb ai/a, 5 applications with a 14-day interval.
Canola: 0.45 lb ai/a,1 application
turf/ornamentals: 1 lb ai/a, 4 applications with a 10-day interval.

Avian NOAEC: 50 ppm based on bobwhite quail.
Mammalian NOAEC: 300 ppm based on rat.

Table III
Revised Avian Chronic Risk Assessment
(Based on Average Kenega values and Maximum Application Rates)

Crop	Short Grass		Tall Grass		Broadleaf Plants/Insects		Seeds/sm. Insects	
	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ
Snap beans	64	1.3	27	0.5	34	0.7	5.3	0.1
lettuce	111	2.2	47	0.9	59	1.2	9	0.2
Raspberries	159	3.2	68	1.4	84	1.7	13	0.3
Onions	113	2.3	48	1.0	60	1.2	9	0.2
Canola	38	0.8	16	0.3	20	0.4	3	0.0
Turfgrass/ Ornamentals	133	2.7	56	1.1	70	1.4	11	0.2

Table IV
Revised Mammalian Chronic Risk Assessment
(Based on Average Kenega values and Maximum Application Rates)

Crop	Short Grass		Tall Grass		Broadleaf Plants/Insects		Seeds/sm. Insects	
	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ
Snap beans	64	0.2	27	0.0	34	0.1	5.3	0.0
Lettuce	111	0.4	47	0.2	59	0.2	9	0.0
Raspberries	159	0.5	68	0.2	84	0.3	13	0.0
Onions	113	0.4	48	0.2	60	0.2	9	0.0
Canola	38	0.1	16	0.0	20	0.1	3	0.0
Turfgrass/ Ornamentals	133	0.4	56	0.2	70	0.2	11	0.0

EEC's based on average Kenega values for maximum application rates and number of applications with the shortest application interval. Degradation is taken into account with a 7-day foliar dissipation half-life, as reported by BASF in the rebuttal, using the TEREEC program.

Snap beans: 0.5 lb ai/a, 2 applications with a 7-day interval.
Lettuce: 1 lb ai/a, 3 applications with a 14-day interval.
Raspberries: 1 lb ai/a, 4 applications with a 7-day interval.
Onions: 1 lb ai/a, 5 applications with a 14-day interval.
Canola: 0.45 lb ai/a,1 application
turf/ornamentals: 1 lb ai/a, 4 applications with a 10-day interval.

Avian NOAEC: 50 ppm based on bobwhite quail.
Mammalian NOAEC: 300 ppm based on rat.

Maximum rates resulted in RQs exceeding avian chronic LOCs for all uses but lower risk to mammals. Using average Kenega values resulted in chronic risks to avian species and low risk to mammals. However, endocrine disruption to these species is still of concern.

REVISED ACUTE AQUATIC ASSESSMENT

The GENEEC computer program was used to calculate the Generic EEC values. GENEEC is a program designed to calculate a generic dissolved pesticide concentration (GEEC) value resulting from surface runoff from a ten hectare field into a one hectare by two meter deep body of water. The program assumes that runoff is sufficient to remove 10% of the pesticide from the ten hectare area. The dissolved pesticide concentration is reduced by adsorption of the pesticide to soil or to organic matter;

the adsorption amount is estimated by the organic carbon partition coefficient (K_{oc}). The dissolved pesticide concentration is also reduced by degradation in the field prior to a rainfall/runoff event (half-life). The program also assimilates incorporation depth at time of application. In this case, ground and aerial application without any incorporation was used. Spray drift values of 1% and 5% are assumed with ground and aerial applications, respectively. The water solubility is also taken into account as well as other aspects of the environmental fate of the chemical (if available) such as, aerobic aquatic metabolic half-life, pH 7 hydrolysis, and the photolysis half-life. Maximum application rates and minimum interval values are used in the model to calculate EECs as worst case scenarios.

The following are the GENEEC model inputs:

Water solubility = 2.6 ppm
Percent spray drift assumed = Ground (1%) or aerial (5%) application
Incorporation depth = 0 inches
Hydrolysis at pH 7 = 1.3 days
Photolysis half-life = 27.2 days
Aerobic soil metabolism = 53 days
Koc value = 451

The following toxicity data was used to calculate aquatic RQs:

Species	Compound	Toxicity Endpoint/ Toxicity Classification	MRID#	Classification
Sheepshead Minnow	BAS 352F	96 hr LC50=>3.5 ppm Moderately Toxic	444299-01	Core
Mysid Shrimp	BAS 352F	96 hr LC50=1.8 ppm Moderately Toxic	444299-03	Core
Oyster	BAS 352F	96 hr LC50=3.5 ppm Moderately Toxic	444299-02	Core

Estuarine and Marine Fish

The acute risk quotients are tabulated below.

Risk Quotients for Estuarine/Marine Fish based on a sheepshead minnow 96 hr LC50 of 3.5 ppm.

Crop/Application rate/ # applications/interval	GENEEC Peak (ppm)	Acute RQ (EEC/LC50)
Snap beans/0.5 lb ai/a, 2 aerial applications with a 7-day interval	0.022	0.00
Lettuce/1 lb ai/a, 3 aerial applications with a 14-day interval.	0.057	0.02

Risk Quotients for Estuarine/Marine Fish based on a sheepshead minnow 96 hr LC50 of 3.5 ppm.

Crop/Application rate/ # applications/interval	GENEEC Peak (ppm)	Acute RQ (EEC/LC50)
Raspberries/1 lb ai/a, 4 aerial applications with a 7-day interval	0.079	0.02
Onions/1 lb ai/a, 5 aerial applications with a 14-day interval	0.080	0.02
Canola/0.45 lb ai/a,1 aerial application	0.010	0.00
turf/ornamentals/1 lb ai/a, 4 ground applications with a 10-day interval.	0.076	0.02

An analysis of the results indicate that no estuarine/marine fish acute LOC was exceeded for the modeled use patterns. No data were submitted to assess chronic risk.

Estuarine and Marine Invertebrates

Acute risk quotients are tabulated below.

Risk Quotients for Estuarine/Marine Aquatic Invertebrates based on a Mysid 96 hr LC50/EC50 of 1.8 ppm.

Crop/Application rate/ # applications/interval	GENEEC Peak (ppm)	Acute RQ (EEC/LC50)
Snap beans/0.5 lb ai/a, 2 aerial applications with a 7-day interval	0.022	0.01
Lettuce/1 lb ai/a, 3 aerial applications with a 14-day interval.	0.057	0.03
Raspberries/1 lb ai/a, 4 aerial applications with a 7-day interval	0.079	0.04
Onions/1 lb ai/a, 5 aerial applications with a 14-day interval	0.080	0.04
Canola/0.45 lb ai/a,1 aerial application	0.010	0.00
turf/ornamentals/1 lb ai/a, 4 ground applications with a 10-day interval.	0.076	0.04

An analysis of the results indicate that no estuarine/marine invertebrate acute LOC was exceeded for the modeled use patterns. No data were submitted to assess chronic risk.

ENDOCRINE DISRUPTION

EFED has concerns in relation to chronic adverse reproductive effects to mammalian and avian species resulting from exposure to vinclozolin. Chronic levels of concern (LOC's) were exceeded for both birds and mammals for many multiple application use sites. Most multiple use EECs were greater than chronic mammalian and avian NOAECs. A NOAEC of 300 ppm was used to determine risk quotients for mammals. However, other effects have been noted below 300 ppm, implying even greater possible risk (actual NOAEL may be 50 ppm or less, similar to avian levels). Effects that occurred under laboratory conditions were at concentrations lower than residue levels expected to be found on wildlife food items in the field. EFED believes that these data must be taken under serious consideration while assessing this compound's eligibility for reregistration.

Vinclozolin has been shown *in vitro* and *in vivo* to be a potent mammalian anti-androgenic compound, inhibiting androgen receptor binding and gene expression (Kelce and Wilson, 1997; Kelce et al., 1997; Gray et al., 1994). Metabolites of vinclozolin (M1 and M2) have also been suggested as anti-androgenic (Klinefelter and Kelce, 1994; Kelce et al., 1994). Gray et al. (1994) found that reproductive effects ranged from infertility, reduced ejaculated sperm counts and hypospadias at 50 and 100 mg/Kg/d, to subtle reductions of anogenital distance at 3 and 6 mg/Kg/d. At the intermediate doses, retained nipples and reduced ventral prostate and seminal vesicle weights were detected. These data demonstrate that at dose levels of vinclozolin 15-fold below dose levels that reduced fertility, the compound shortened anogenital distance and reduced sex accessory gland weights.

Thus, the following language should be added to the RED chapter:

EPA's DRAFT Interim Policy for Potential Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, Vinclozolin may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption in wildlife.